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Effect of nurse-led care on quality of care and level of HbA1C in patients with diabetic foot ulcer: A randomized clinical trial

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Abstract

Diabetic foot ulcer (DFU) is a serious and costly complication in diabetes which affects different aspects of life and can reduce patient's quality of life. Various views to manage DFU have been introduced. The nurse-led team, as a multidisciplinary team, can be effective due to a holistic approach to some disease management; but in patients with DFU it has not been assessed. Therefore, this study was designed to determine the effect of nurse-led care on quality of care (QOC) and improvement of HbA1C in Patients with DFU. This was a randomized clinical trial study performed on 52 patients with DFU. Patients were randomly assigned into two groups: nurse-led care intervention and standard care. The study was conducted in one of the hospitals affiliated to Tehran University of Medical Sciences. Data were collected using two questionnaires: Demographic characteristics and Quality Patient Care Scale (QUALPACS) and taking a blood sample for HbA1C. The nurse-led Care interventions were conducted in three stages: Integrated, Interdisciplinary, and Comprehensive. Descriptive and analytic statistical methods were used to analyze the data. $P < .05$ was considered significant. The results demonstrated that according to repeated measures test, (before, 4 and 12 weeks after the intervention), the level of QOC dimensions (Psychosocial, communication and physical aspect) in the nurse-led group had a significant difference with control group ($P < .0001$). Also, according to the results of Independent *t* test, there was a significant difference in total QOC scoring and HbA1c between intervention and control groups after the intervention and follow up ($P < .0001$). Considering the burden of diabetes and DFUs, it seems that the establishment of a nurse-led care approach can be an effective strategy to manage and treat these patients, and eliminate the disruption of care and achieve optimal care quality.

1 | INTRODUCTION

One of the most severe complications for patients with diabetes mellitus (DM) is the diabetic foot ulcer (DFU) which can lead to gangrene, amputation, loss of quality of life, longer hospitalization time, increased costs, and even death.[1] The burden of diabetic foot disease is expected to increase in the future since the contributory factors to foot disease, such as peripheral neuropathy and vascular disease, are present in more than 10% of people at the time of diagnosis of type 2 diabetes, and the first year after diagnosis of diabetes is a period of danger for foot ulcers and amputation.[2] Statistics show that one out of every five patients with diabetes who have been referred to a hospital has had a foot problem, and it has been estimated that 4% to 10% of people with diabetes develop foot ulcer.[3,4] In UK, 50% of the causes of hospitalization in patients with diabetes are DFU.[5] The results of Iranian studies indicate that 20% of cases of diabetic patients are due to DFU.[6] In addition, according to the findings, the incidence of lower limb amputation in diabetic patients is 10 to

30 times higher than that of nondiabetic patients. Worldwide, an amputation occurs somewhere in the world every 20 seconds because of diabetes.[7]

The main approach to reducing the incidence of diabetic foot and its outcome is to prevent and diagnose it in a timely manner. Obviously, careful attention to foot care and rapid management of minor foot injuries are key to preventing it.[8] Also adjusting HbA1c levels is important for reducing DFU and its progression too. Kim HS showed that 1% decrease in glycosylated hemoglobin can lead to a 35% reduction in complications.[9]

In some countries, there are specific guidelines for the prevention and screening of diabetic patients, which is done with the participation of a multi-disciplinary diabetic foot care team in the hospital and in the community.[10-13] The combination of these teams includes a diabetes specialist, surgeon, and nurse specializing in diabetes.[10] These teams will be led by one of the team members.

However, due to the need for nurses to prevent wounds and care for foot ulcers,[9] most teams are referred to as nurse-led teams who have a pivotal role in leading nurses.[14] In fact, nurse-led is a term that refers to a nurse with specific tasks who fully care for the patient in accordance with the protocol, guidelines and instructions, and with high-quality. In this approach, the nurse responsible for overall coordination, management and continuity of care is a specific part of treatment or intervention.[15] In this method, nurses have a holistic view of the patient, which in turn can improve the patient- nurse relationship, patient satisfaction, follow up care, diagnosis and timely treatment of patients' problems and their faster recovery.[14] However, despite the benefits of this method, it has not yet been used in a developing country and middle income countries like Iran.

Furthermore, it has been claimed that teamwork can improve the quality of care (QOC). QOC is defined as fulfilling physical needs by providing professional care, psychosocial support, satisfaction with care, and ensuring comprehensive and comprehensive care to the patient.[18] Several studies have shown that improving the QOC can increase the patient's compliance with the treatment program, increase patient independence, reduce anxiety, mortality, and disease complications.[15-19]

Since care is the core of nursing, it seems that presenting a specialized task as a nurse-led one will promote nursing profession's independence.[24] However, the nurse considers the role of caring, decision-making, support, being protective, managerial, offering rehabilitation, relaxing, coordinating, communicating, educating; currently the role of nursing therapists is the only acceptable role for the health system.[25] While the results of the studies indicated that the care provided to patients was not desirable,[20-22] so nurse-led care can be considered as one of the proposed strategies for eliminating care disruption and achieving optimal care quality.

The nurse-led method is being implemented in different countries such as Australia, United States and England in critical care or general wards.[23-27] Just in northern Colorado and UK, is this approach underway to care for diabetic foot patients with specific guidelines,[28] and studies have been done on this issue.[29]

Most studies have been conducted on the effectiveness of nurse-led care in the Western and European countries.[30] The results of these studies (contradictory or shown to be effective) indicate the effectiveness of this method. These studies were also highly methodologically diverse. But in most countries such as Iran, this approach has not been studied in diabetic patients who are always in need of follow-up, ongoing care, and monitoring. While, in our context as a developing country, our health system is culturally and even structurally different from the developed countries. Therefore, considering the importance of the issue, we aimed to determine the effect of nursing-led care on the QOC and improvement of HbA1c in patients with DFUs.

2 | METHODS

This was a randomized clinical trial[1] study performed on 52 patients with DFU that was conducted in Shariati hospital (Educational) of Tehran, Department of Endocrinology, over a 1-year period (2017-2018). Sample size of 26 patients in each group was selected to achieve at least 80% power (84% actual) in order to detect a difference between the group proportions of 0.45. The proportion in group 1 (nurse-led group) was assumed to be 0.35 under the null hypothesis and 0.8 under the alternative hypothesis. The proportion in group 2 (control group) was 0.35. The significance level actually achieved by this design was 0.052.

Inclusion criteria were adults with diabetes being referred to treat ulceration and aged 18 years or older. Excluded were patients with cognitive impairment, psychiatric diseases, GFR < 30 mL/min/1.73 m^3, and Hb A1C > 12%.

The allocation was conducted by examiner. The investigator completed an enrollment form. This form included data on the subjects' inclusion and exclusion criteria. The examiner randomized the patients according to the predefined criteria above and this information was provided to the investigator. Randomization is done once at the enrollment of study. At randomization after the enrollment, participants were indiscriminately assigned into two groups of nurse-led care intervention and standard care by blocked randomization. After confirming eligibility and providing written informed consent all participants took part in the baseline data collection.

Data were collected using two questionnaires; the first one included some questions about the samples' demographic characteristics and the factors related to their illness. The second part consisted of the three aspectual Quality Patient Care Scale (QUALPACS). Psychosocial (32 questions), physical (23 questions), and communicational (14 questions) aspects were assessed using four possible choices of always (four points), often (three points), sometimes (2 points) and Never (1 point). Quality care scores in this questionnaire ranged from 68 to 272. Scores of 68-136 were interpreted as undesirable, 137-204 as partly undesirable and 205-272 as desirable. This questionnaire has been used to evaluate care process and quality of nursing care since 1975 in the United States, England, and Nigeria. The reliability and validity of the Persian version of questionnaire were confirmed in 2005 in Tabriz.[31] To determine the validity, the questionnaire was evaluated again by a group of professors and experts in this

TABLE 1 Demographic characteristics of patients with diabetic foot ulcer participated in the study

Variables		Intervention N (%)	Control N (%)	*P* value
Gender				
	Male	*12 (46.15)*	*13 (50)*	.50
	Female	*14 (53.85)*	*13 (50)*	
Marital status				
	Married	*26 (100)*	*21 (80.76)*	.09
	Single	*0 (0)*	*5 (19.24)*	
Employment status				
	Housewife	*10 (38.46)*	*3 (11.54)*	.015
	Employed	*11 (42.31)*	*9 (34.61)*	
	Unemployed	*4 (15.38)*	*5 (29.24)*	
	Retired	*1 (3.85)*	*9 (34.61)*	
Body mass index (BMI)				
	Normal	*3 (11.54)*	*2 (7.69)*	.24
	Slim	*0 (0)*	*0 (0)*	
	Excess weight	*11 (42.31)*	*13 (50)*	
	Obese	*12 (46.15)*	*11 (42.31)*	
Type of treatment				
	Insulin	*14 (53.85)*	*7 (30.76)*	.057
	Oral medications	*12 (46.15)*	*18 (69.24)*	
History of foot ulcer				
	Yes	*22 (84.61)*	*16 (61.54)*	.08
	No	*4 (15.39)*	*0 9(38.46)*	
Location of foot ulcer				
	Under the big toe	*9 (38.46)*	*13 (50)*	.23
	Metatarsus	*13 (50)*	*7 (26.92)*	
	Heel	*4 (11.54)*	*6 (23.08)*	
Number of foot ulcers				
	One	*18 (69.23)*	*16 (61.54)*	.18
	Two	*5 (19.23)*	*6 (23.08)*	
	Three	*1 (3.85)*	*0 (0)*	
	Four	*2 (7.69)*	*3 (15.38)*	

TABLE 2 Level of HbA1C in two groups (Mean ± SD)

Group time			Intervention	Control	Independent *t* test
Before intervention	Mean		9.35 ± 0.90	9.52 ± 1.12	t = −5.9 df = 50 *P* = .552
	Median		9.20	9.90	
	Quartile	**25**	8.80	8.45	
		50	9.20	9.90	
		75	10.10	10.40	
After intervention	Mean		8.7 ± 0.63	9.8 ± 0.83	t = −5.3 df = 50 *P* < .0001
	Median		8.60	9.90	
	Quartile	**25**	8.20	9.02	
		50	8.60	9.90	
		75	9.00	10.55	
Paired t test			t = −3.2 df = 25 *P* = .003	t = 0.94 df = 25 *P* = .356	-

field. A test-retest method was used to determine the reliability of the questionnaire. In addition, Cronbach's alpha coefficient was also used to determine the internal consistency of the questionnaire. Cronbach's alpha coefficient was 0.94.

Baseline data were collected in order to ensure unbiased data collection with respect to group assignment (demographic data, medical data, and data about foot ulcer, QOC). Medical data consisted of diabetes type and duration, Hemoglobin A1c, body mass index (BMI).

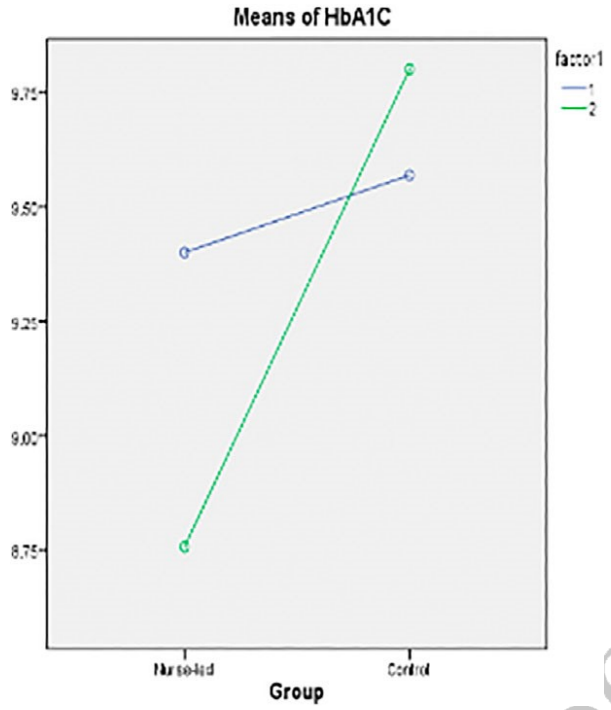
After determining the eligible patients, their random allocation to the groups and pretest and taking blood samples for HbA1C test, intervention was done by double-blind (participants and questioner for blindness intervention). Also, the effect of confounding variables such as GFR,[2] blood sugar, hemoglobin, and ulcer grading were controlled at the beginning of the study by the inclusion and exclusion criteria.

The intervention was coordinated by the researcher as a specialist nurse and was conducted by a treatment team consisting of nurses, endocrinologist, and orthopedic surgeon (to assess bone disorders), general surgeon (deep debridement and vessel disorders), Forensic medicine (to prevent legal problems) and researcher (as a coordinator). In this group, nurse-led care interventions were conducted in three stages: integrated, interdisciplinary, and comprehensive.[32]

In the integrated phase, provision of care was done step by step in accordance with the Guideline for Care of DFUs.[33] Monitoring and evaluation of wounds, offloading, proper procedures, and wound dressing, blood glucose control and hemodynamic status of patients, coordination and management of specific cases, provision of basic care, patient education and self-care were the activities of this phase.

In the interdisciplinary phase, the counseling required by the treatment team was performed. In addition, patient referral for those with grade 3 and 4 wounds was done to expedite wound healing, debridement or surgery. At this stage (4 weeks after the intervention), posttest and comparison of the groups were performed using QUALPAC questionnaire.

In the comprehensive phase, support, education, self-care and a more comprehensive description was provided to the patient and their caregivers. Also, follow-up by the researcher was conducted in person and on the phone, monitoring of all stages included the actions



Q16 [Color figure can be viewed at wileyonlinelibrary.com]

FIGURE 1 Level of HbA1C in two groups [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 3 Psychosocial dimension of quality of care in two groups (Mean ± SD)

Group Time			Intervention	Control	Independent *t* test	Intervention effect repeated measures
Before intervention	Mean		44.34 ± 7.56	45.44 ± 11.39	t = –0.42 df = 50 *P* = .67	F = 26.20 df = 1 *P* < .0001
	Median		45	43		
	Quartile	**25**	39	42.50		
		50	45	43		
		75	51	50.25		
After intervention	Mean		70.42 ± 11.97	53.40 ± 10.99	t = 5.28 df = 50 *P* < .0001	
	Median		73	56		
	Quartile	**25**	67	49		
		50	73	56		
		75	80	58		
Follow up	Mean		78.84 ± 6.80	61.92 ± 5.92	t = 9.42 df = 50 *P* < .0001	
	Median		80	60		
Q7	Quartile	**25**	76	59		
		50	80	60		
		75	83	61		

of this phase and was done by the researchers. This phase lasted until the 12th week, reassessment of the groups by QUALPAC questionnaire and re-taking the blood sample to evaluate HbA1c at the end of the 12th week was done.

Also, the control group received routine care (the General physician pays attention to complaints, glucose regulation, current cardiovascular risk, and the early identification of complications), all the routine interventions were recorded, but the researcher did not play a role in changing or directing the routine care in the control group. They will be offered an opportunity to join the training program at the end of the study.

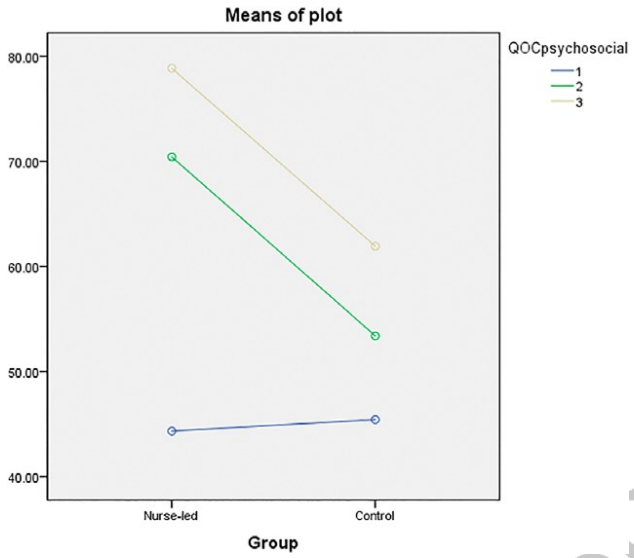


FIGURE 2 Psychosocial dimension of quality of care in two groups [Color figure can be viewed at wileyonlinelibrary.com]

Data analysis were done using SPSS software version 16 through descriptive and inferential statistics such as Chi-square, paired *t* test, independent *t* test, and repeated measures. Also, at the beginning of the study, we were going to apply the intention to treat approach and the per protocol support method for data analysis. But at the end, there were not any missed values, so the two methods were the same.

3 | ETHICAL CONSIDERATIONS

The study was approved by the Ethics Committee of the Tehran University of Medical Sciences/Ethics Committee on Research in Nursing and Midwifery Faculty and Faculty of Rehabilitation. Furthermore, researchers followed the Helsinki Declaration for medical research including on human subjects. An informed written consent form was signed by each participant. The participants were assured that talking part in this study was voluntary and they can quit at any time and all information will remain confidential. The study was registered at the Iranian Registry of Clinical Trials (IRCT), available at http://irct.ir/, with registration number of "IRCT20100628004256N8."

4 | RESULTS

The characteristics of 52 subjects (26 interventions and 26 controls) are described in Table 1. It shows the distribution of samples according to their age, gender, occupational status, location, economic status, BMI, type of treatment, DFU background, location, and the number of foot ulcers. The obtained mean and SD of age of participants in intervention and control group was (64.26 ± 9.40 and 59.69 ± 9.23) respectively. The socio-demographic characteristics

TABLE 4 Communication dimension of quality of care in two groups (Mean ± SD)

Group time			Intervention	Control	Independent *t* test	Intervention effect repeated measures
Before intervention	Mean		21.19 ± 3.84	22.52 ± 6.42	t = –0.82 df = 50 *P* = .41	F = 22.22 df = 1 *P* < .0001
	Median		22	21		
	Quartile	**25**	17	19		
		50	22	21		
		75	25	26		
After intervention	Mean		34.76 ± 4.40	26.92 ± 4.07	t = 6.60 df = 50 *P* < .0001	
	Median		36	27		
	Quartile	**25**	31	26		
		50	36	27		
		75	38	28		
Follow up	Mean		36.88 ± 3.1	29.24 ± 3.84	t = 7.76 df = 50 *P* < .0001	
	Median		39	28		
	Quartile	**25**	34	27		
		50	39	28		
		75	39	29		

were similar between two groups except employment status and showed no significant difference ($P > .05$). Kolmogorov-Smirnov test was used to investigate the normal distribution of data and based on the KS results, parametric tests were used to analyze the data. Findings of this study showed that before and after the intervention the level of HbA1C in the nurse-led group was (9.35 ± 0.90 and 8.7 ± 0.63) and in the control group was (9.52 ± 1.12 and 9.8 ± 0.83) and according to the results of Independent *t* test, there was not a statically significant difference before intervention between two groups.

Paired *t* test was calculated to assess the effect of nurse-led intervention on HbA1C in each group. Independent *t* test was used to compare two groups (intervention and control), and a statically significant difference was indicated ($P < .0001$) between intervention and control group, after the intervention (Table 2, Figure 1). It should be noted that we controlled confounding variables such as infection (as an inclusion criteria) and GFR (control group: 64.33 ± 17.40, nurse-led group: 72.83 ± 25.03 and $P > .05$). Then, by comparing two groups, the observed statistical differences can be attributed to the effect of intervention.

Furthermore, in nurse-led group, according to psychological score of QOC was Undesirable before and after the intervention, and in follow up, this score changed to partly desirable. But control group had undesirable QOC scoring in baseline and did not change its level after intervention and in follow up, and according to the results of the repeated measures test, there was significant difference in the level of scoring psychological aspect of QOC in the intervention (effect of intervention before, after and at follow up) ($P < .0001$) (see Table 3, Figure 2).

Participants in nurse-led group according to communicational aspect score of QOC, had undesirable QOC scoring before intervention, and after the intervention and follow-up had partly desirable score, but control group had Undesirable QOC scoring in baseline and after intervention, but in follow up changed to partly desirable. According to the results of the repeated measures test, there was significant difference in the level of scoring communicational aspect of QOC in the intervention (effect of intervention before, after and at follow up) ($P < .0001$) (see Table 4, Figure 3).

Also, participants in nurse-led group according to the physical aspect score of QOC, had undesirable QOC scoring before intervention and after the intervention and at follow up party desirable score was attained, but control group had undesirable QOC scoring in baseline and after intervention, but, in follow up this changed to party desirable, and according to the results of the repeated measures test, there was significant difference in the physical aspect score of QOC in the intervention (effect of intervention before, after and at follow up) ($P < .0001$) (see Table 5, Figure 4).

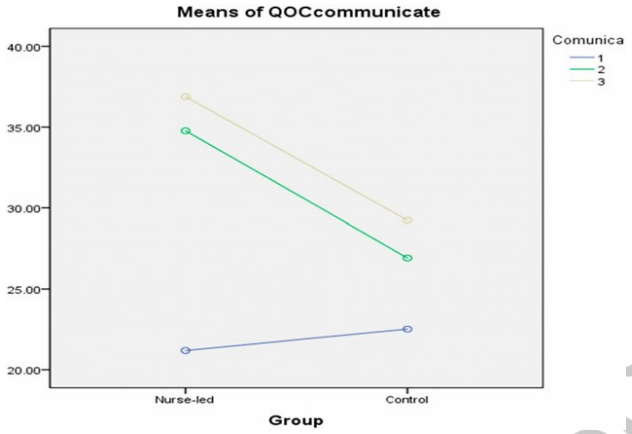


FIGURE 3 Communication dimension of quality of care in two groups [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 5 Physical dimension of quality of care in two groups (Mean ± SD)

Group time			Intervention	Control	Independent *t* test	Intervention effect repeated measures
Before intervention	Mean		38.26 ± 6.21	39.12 ± 9.8	t = –0.36 df = 50 *P* = .72	F = 26.65 df = 1 *P* < .0001
	Median		39.50	39		
	Quartile	**25**	33	36		
		50	39	39		
		75	43	44		
After intervention	Mean		59.84 ± 10.5	45.56 ± 9.55	t = 5.06 df = 50 *P* < .0001	
	Median		61.50	47		
	Quartile	**25**	56	42		
		50	61.50	47		
		75	69	50		
Follow up	Mean		66.00 ± 5.43	51.36 ± 4.83	t = 10.14 df = 50 *P* < .0001	
	Median		67	50		
	Quartile	**25**	64	48		
		50	67	50		
		75	69	51		

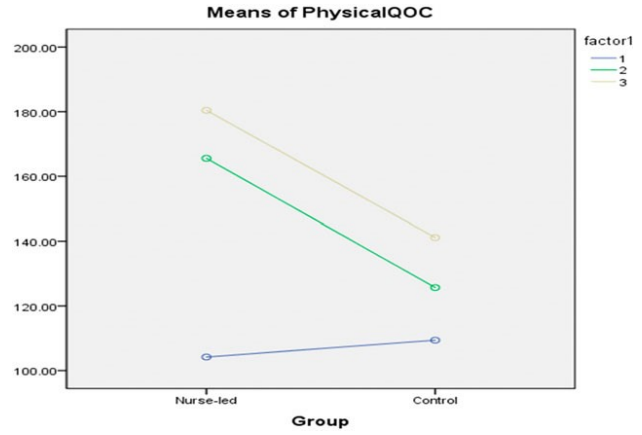


FIGURE 4 Physical dimension of quality of care in two groups [Color figure can be viewed at wileyonlinelibrary.com]

Finally, findings of this study showed that before, after intervention and at follow up, the level of total QOC in the nurse-led and control group was (103.8 ± 16.53, 165.03 ± 25.58 and 181.73 ± 15.04), and (107.08 ± 27.25, 125.88 ± 23.59, and 142.52 ± 14.48), respectively and there was a significant difference in total QOC scoring between two groups after the intervention and at follow up ($P < .0001$).

5 | DISCUSSION

The results of our study indicated that most of the participantes in nurse-led group were obese and married. The location of the wound in these participants was mostly in Metatarsus. Also, participants in the nurse-led group had a history of diabetes of more than 5 years. They had poor glycemic control which can be due to the lack of physical activity, stress, need for a change in medication and infection. These conditions were similar in the intervention and control groups before the intervention and there was no significant difference between the two groups ($P > .05$). But after intervention, the nurse-led group was in better condition than the control group. They had good glycemic control and HbA1C (8.7 ± 0.63) was obtained. While the change in control group before and after the intervention was negligible and according to the results of Independent *t* test, there was a significant difference between the two groups after the intervention ($P < .0001$).

As with many chronic illnesses, the treatment options for DFU involve complex medical regimes that must be carried out on a daily basis. Continuous ancillary measures such as walking, physical therapy, calf exercise, skin care, or leg elevation, assessment and glysemic control, add to the complexity of management.[34] The nurse-led approach has emerged in response to these conditions and coordination, management and continuity of care are the characteristics of this approach.[31] The results of some studies indicated that follow-up care and educational interventions will continue to reduce blood glucose levels and even reduce BMI.[35] Indeed, measuring and controlling blood glucose as a simple and low-cost means of study leads to the identification and monitoring of patients with DFU in terms of rapid healing of wounds and other complications of diabetes. Hyperglycemia and poor glycemic control in these patients results in impaired neutrophil function, diminishing host defense against organisms,[36] which may be a reason for delay in wound healing. It has been mentioned that, the effect of blood glucose control on the process of diabetic would treatment is such that a 1% decrease in glycosylated hemoglobin can lead to a 35% reduction in complications.[37] Carely et al showed that improved glycemic control, diabetic symptoms, and decreased length of hospital stay are the main benefits of nurse-led interventions in diabetes care.[38] Gill et al stated that the implementation of simple protocols and education system in the care of diabetic patients by nurses as nurse-led approach could modify the blood glucose control in these patients.[39] Also, Daly et al in a meta-analysis study on the effect of the nurse-led on HbA_1C reported that, compared to the three meta-analyses, participants in the nurse-led group had a significantly lower HbA1C level than the control group,[40] and emphasized the role of nurses in the management of diabetic patients in uncontrolled glycemic conditions which was similar to the results of the present study. In fact, the most important reason for the effect of the nurse-led intervention in comparison with routine care was the association and continuity of care, monitoring, and control of patients, which was consistent with the results of the above-mentioned studies.

Furthemore, the comparison of two groups of nurse-led and control in this study was made based on the hypothesis that nurse-led intervention as a team can improve level of QOC more than routine care. As repeated measures in this study showed, there was a significant difference between the levels of QOC before, after intervention and in follow up between the two groups ($P < .0001$).

Findings from nursing studies in recent years have shown that QOC is low and nurses rarely participate in nursing care development and improvement programs,[33] which is consistent with the findings of pretest in present study. But after intervention, especially in follow up, patients with DFU in nurse-led group received continuous care, step by step, according to Guideline of care for DFUs, counseling by the treatment team, supportive care, self-care education, follow-up in-person and by telephone with a nurse specializing in diabetes and reported higher QOC scoring than control group that received routine care. The quality of nursing care is influenced by the relationship between the nurse and the patient, the active participation of the patient in decision-making.[41] So, given that establishing communication and interaction is one of the principles of nurse-led intervention,[42] we can attribute the mean difference in psychosocial and communication aspects of QOC in the nurse-led rather than control group to it. Conversely, the patient's understanding of the QOC provided is relevant to the nature of the illness, the duration of hospitalization and the outcome of the recovery. This means that satisfaction from recovery will prevent dissatisfaction with the QOC.[43] Therefore, lower mean score of the physical aspect compared to other dimensions of QOC can be considered as the time for the improvement of DFU despite wound healing in these patients.

Participants in the control group received routine care and education during admission, but nurses in control group were more

concerned with scientific and skill aspects than art of nursing. This is the same separation between theory and practice that is heavily seen in our nursing profession.[30] If we accept that effective nursing (by nurse specialists in diabetes) is equivalent to better care and a better understanding of care, we can claim that QOC is guaranteed.[44] Moreover, since the QOC provided is a determining factor in the patient's recovery,[30] it is possible to improve the health of the patient too.

Significant positive associations between effective styles of leadership and high levels of patient satisfaction and reduction of adverse effects have been reported.[45] The study conducted by Keller-Senn and colleagues, in Switzerland, in 2015 showed that nurse-led education program enhanced foot care self-efficacy of patients. Therefore, support for nurses in the provision of continuous care is considered necessary.[46] Also, Alexandra Garcia in 2016 studied nurse-led screening protocol as an intervention and a strategy for improving the QOC, monitoring of symptoms and conditions of patients, providing training to facilitate admission and change in lifestyle and provide cohesive care and emphasized the need for the implementation of the protocol for screening and prevention of foot ulcer and its complications.[47] Sfantou reported that Leadership styles were found to be strongly correlated with quality care and associated measures.[48]

There is no study in this field or review of the QOC provided.[49,50] But, a nurse-led intervention is being used in patients with pneumonia, hypertension and in different countries such as Australia, the United States[28,41] and, in the UK, nurse-led care is underway as a specific strategy for the patients with DFU who need to be hospitalized[25]; further, it is stated that they had a positive impact on patient care which is in line with the results of the present study.

6 | LIMITATIONS

In the present study, in the integrated phase, provision of care was done step by step in accordance with the Guideline for Care of DFUs. But the effects of offloading and procedures have not been evaluated separately and we recommend that it be considered in future studies. Also, given that our intervention lasted for 3 months in patients with foot ulcer, and the evaluation of ulcers with recurrence or screening was not the purpose of the present study, we could not analyze them. Therefore, it is suggested that a study on screening and recurrence of ulcers be performed in patients with DFU, in view of the positive effect of nurse-led approach.

7 | CONCLUSIONS

The results of this study showed that fulfilling needs by performing professional care, psychosocial support, satisfaction of care and ensuring comprehensive care to the patient with continuous support by specialized nurses, counseling and coordination with contributors is possible. Then, with regard to the burden of diabetes and DFUs, its optimal organization and management through the provision of advanced and accurate care, follow-up care programs, monitoring of patient status step by step, drug management and treatment provision are notable and it seems that the establishment of a nurse-led care approach can be an effective strategy to manage these patients, and eliminate the disruption of care and achieve optimal care quality.

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ENDNOTES

[1] RCT

[2] *Glomerular filtration rate*

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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